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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/753,119	01/06/2004	Loren John Hoffbeck	P06284US01	5211

22885 7590 02/23/2005

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DES MOINES, IA 50309-2721

EXAMINER	
FOX, DAVID T	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 02/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/753,119	HOFFBECK, LOREN JOHN	
	Examiner	Art Unit	
	David T. Fox	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/6/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The copies of the PTOL-1449 and 892 forms from the parent application have been received. However, the Examiner is unable to transfer the 892 forms from the parent application into the instant application. Applicant is requested to submit a supplemental information disclosure statement citing those references previously cited on the 892 forms in the parent application.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 8 of U.S. Patent No. 6,720,487. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one of ordinary skill in the art to utilize the method of producing an F1 hybrid with PH4GP as one of the parents as claimed by the patent, to obtain the resultant F1 hybrid as instantly claimed.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to any F1 hybrid produced by crossing a single inbred parent PH4GP with any of a multitude of unspecified second parents, wherein half of the genetic composition of the hybrid is contributed by the first inbred parent. Claims 7-10 are drawn to F1 hybrid plants which somehow contain an intact cell from an inbred parent.

In contrast, the specification only provides guidance for the traits exhibited by the single inbred parent PH4GP, and for traits exhibited by crossing the single inbred parent PH4GP with three other inbred parents (see Tables 3A-3B and 4). No guidance is provided regarding the genetic composition of PH4GP at any locus or on any chromosome. No guidance is provided regarding the genetic composition of any of a multitude of non-exemplified inbreds or hybrids at any single locus or on any chromosome. Furthermore, no guidance is provided for the obtention or characterization of a hybrid plant which somehow contains an intact cell from an inbred parent.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed

subject matter sufficient to distinguish it from other materials." University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id. Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." Id.

See MPEP Section 2163, page 156 of Chapter 2100 of the August 2001 version, column 2, bottom paragraph, where it is taught that

> [T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus of sequences as broadly claimed, or plants containing them. Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of the claimed invention at the time of filing. See the Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111.

See also Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn to any F1 hybrid produced by crossing a single inbred parent PH4GP with any of a multitude of unspecified second parents, wherein half of the genetic composition of the hybrid is contributed by the first inbred parent. Claims 7-10 are drawn to F1 hybrid plants which somehow contain an intact cell from an inbred parent.

In contrast, the specification only provides guidance for the traits exhibited by the single inbred parent PH4GP, and for traits exhibited by crossing the single inbred parent PH4GP with three other inbred parents (see Tables 3A-3B and 4). No guidance is provided regarding the genetic composition of PH4GP at any locus or on any chromosome. No guidance is provided regarding the genetic composition of any of a multitude of non-exemplified inbreds or hybrids at any single locus or on any chromosome. Furthermore, no guidance is provided for the obtention or characterization of a hybrid plant which somehow contains an intact cell from an inbred parent.

The use of breeding crosses to obtain a particular desirable corn individual possessing a particular genetic and morphological complement of traits is unpredictable, due to the large number of genes involved, and the interaction of these

genes with selection methods, environmental effects, breeder actions. See Kevern (US 5,850,009, column 4, lines 37-46). Moreover, the usefulness of a multitude of hybrids produced by crossing a single inbred with a multitude of non-exemplified breeding partners is unpredictable, given the polygenic nature of inheritance of many agronomic traits, the difficulty in predicting the expression of said traits in hybrid progeny of inbreds which do not express them, and the failure of those collections of traits to be transmitted to progeny of parents containing them (see, e.g., US 5,763,755 to Carlone, paragraphs bridging columns 1 and 2).

In addition, corn breeding is confounded by unpredictable epistatic effects, including genetic interactions and environment X genotype interactions, which prevent the prediction or recovery of plants with desirable increases in yield and other agronomic traits. Stuber et al teach that grain yield and ear number were strongly affected by environmental influences such as plant density, and that epistatic genetic interactions prevented accurate performance prediction of particular hybrids derived from particular crosses (see, e.g., page 503, Abstract; page 505, column 1, first and third full paragraphs; page 506, paragraph bridging the columns). Melchinger et al teach that epistatic effects reduced the amount of heterosis (hybrid vigor measured by increased grain yield and overall plant health) in hybrid crosses (see, e.g., page 231, column 1, bottom paragraph; column 2, first paragraph of Introduction; page 233, column 2, bottom paragraph; page 237, column 1, top paragraph).

Furthermore, it is well known in the art that hybrid plants are produced by the fusion of a haploid sperm cell and a haploid egg cell from inbred parents, to form a

diploid embryo. Upon said fusion, the sperm and egg cells from the inbred parents cease to exist. The plant resulting from the diploid embryo may contain genetic material from both parents, but does not contain any intact egg or sperm cell (or any other type of cell) from the inbred parents. Thus, it is unlikely and therefore unpredictable that the plants of claims 7-10 could be obtained.

Given the claim breadth, unpredictability and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to evaluate the genomes of PH4GP or a multitude of multitude of non-exemplified inbreds or hybrids produced by crossing PH4GP with a multitude of non-exemplified second parents. Undue experimentation would have also been required to evaluate the traits exhibited by a multitude of non-exemplified hybrids produced by crossing PH4GP with a multitude of non-exemplified second parents, or to obtain an F1 hybrid plant which somehow contains an intact cell from PH4GP.

The claims are deemed free of the prior art, given the failure of the prior art to teach or suggest PH4GP or methods of its use to produce a hybrid therefrom, as stated in the allowed parent application.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is 571-272-0795. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy J. Nelson, Ph.D., can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

February 21, 2005

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638